## REMARKS

### The 35 U.S.C. § 112 Rejection

As indicated in the Advisory Action, the amendments made in the Reply of August 8, 2003 – which is now entered – overcome the 35 U.S.C. § 112 rejection.

### The Restriction Requirement

Claims 7, 10, 17 and 20 are withdrawn due to an election of species requirement and are not restricted.

Claims 23-31 and 35 are directed to kit claims and these claims have been restricted from the composition claims despite that the kit claims recite the exact same ingredients as the composition claims. Applicants reiterate their traversal of the restriction requirement. Although separate classification, alone, is not sufficient basis for restriction anyway, applicants do not believe that these inventions would be separately classified. The original restriction in the Office Action of November 18, 2002, states that the kits would be classified in Class 206. But this class is for "Special receptacles and packages." Applicants' kit claims are not characterized by the nature of the receptacle or package but by what is contained in the kit. The receptacle or package used for applicants' kit would be any of those well known in the art. The invention obviously lies in the contents of the kit as does the invention of the compositions. Thus, applicants are hard pressed to see why the search would be different or why the restriction should be maintained.

Additionally, as pointed out before, applicants had clearly refuted the originally alleged basis for the restriction, yet the restriction is still being maintained with no new proper basis being alleged. Contrary to the statement in the Advisory Action, applicants arguments traversing the restriction were not addressed in the Final Office Action. The

Examiner agreed that the claimed compositions, methods and kits are obviously closely related but maintained the restriction apparently solely due to alleged separate classification. But separate classification alone if never sufficient basis for restriction.

For these reasons, it is again urged that the restriction should be withdrawn.

**The 35 U.S.C. § 103 Rejections**

The two rejections under 35 U.S.C. § 103 are traversed for the reasons stated in the Reply of August 8, 2003, but the following additional comments are provided for emphasis and to address the comments in the Advisory Action.

The Advisory Action alleges that merely because the Miller, Blum and Bannerjee references are all directed to pharmaceutical compositions that it would be obvious to combine teachings of one reference with another. Applicants respectfully disagree that one of ordinary skill in the art would be motivated to modify one pharmaceutical composition by adding elements of any other pharmaceutical composition merely because they are both pharmaceuticals. Under such a test, no combination of two known pharmaceutical ingredients could ever be patentable. This cannot be the proper test. As stated in Intra Corp. v. Hamar Laser, 4 USPQ2d 1337, 1352 (E.D.Mich. 1987), *aff'd*, 862 F.2d 320 (Fed. Cir. 1988)(unpublished): "Most patentable inventions combine old elements .. [and such] fact .. is irrelevant to the legal determination of obviousness under § 103..". See also In re Rouffet, 149 F.3d 1350, 47 USPQ 2d 1453 (Fed. Cir. 1998), and the previously cited In re Laskowski; and In re Geiger.

There is no desirability indicated in the references, i.e., no motivation, for why one of ordinary skill in the art would want to adjust the tonicity of the Miller or Blum compositions by applying the method of Bannerjee. First, there is no teaching in Miller or Blum to suggest

that there is any need or desire to adjust the tonicity of their compositions. There is also no teaching in Miller or Blum which would lead one of ordinary skill in the art to believe: 1) that a tonicity adjusting agent would not, in fact, be harmful to the objectives of the Miller or Blum inventions or 2) that a tonicity adjusting agent for bronchodilating compositions would be useful for a radiopharmaceutical composition. The compositions of Bannerjee are completely unrelated to those of Miller and Blum in terms of constituents, activities and applications and thus there is no reasonable expectation that the tonicity adjusting agent of Bannerjee would work in the completely different radiopharmaceutical compositions.

The Advisory Action further alleges that the two iodide agents from the list of about 70 in Bannerjee are conventional tonicity adjusting agents added to saline solutions. However, Bannerjee does not evidence that this is the case nor does it point to the use, particularly, of the iodide agents over the many other types of agents disclosed therein. Thus, there is no motivation for one of ordinary skill in the art to choose particularly the iodide agents from the many disclosed by Bannerjee.

Additionally, it is submitted that, even if one of ordinary skill in the art would have combined Miller or Blum and Bannerjee, the claimed invention would still not be suggested. Even if there was a desire to use the tonicity adjusting embodiments of Bannerjee, such combination would not suggest the use of an iodide tonicity adjusting agent in an amount sufficient to "stabilize the composition against degradation thus maintaining high radiochemical purity of the composition." Bannerjee obviously teaches nothing about the stabilizing effect of iodide in a radiopharmaceutical, as discovered by applicants. The Advisory Action alleges that if the combination of Bannerjee is made, the resulting stabilizing by the iodide would inherently occur. Applicants respectfully disagree. Inherency in the patent law is generally defined as a phenomena which necessarily and inevitably

occurs, as opposed to a phenomena which might occur, from a given set of conditions. Ex Parte Cyba, 155 USPQ 756 (Bd. App. 1966); and In re Oelrich, 212 USPQ 323, 326 (CCPA 1981). Adding the tonicity adjusting agent of Bannerjee would not "necessarily and inevitably" result in stabilizing a radiopharmaceutical. For example, the amount for tonicity adjustment would not "necessarily and inevitably" be a sufficient amount for radiopharmaceutical stabilization.

For the above reasons, and for those previously made in the Reply entered concurrent with the RCE filing, it is urged that the instant claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

In view of the above, favorable reconsideration is courteously requested. If there are any remaining issues which can be expedited by a telephone conference, the examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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